REMARKS

Claims 1, 41, and 45 have been amended to specifically recite that the claimed catheter device (claim 1) and nasogastric tube electrodes (claims 41 and 45) are designed for stimulating the vagus nerve. Applicant believes that this element was clear from the claims as formerly written and does not comprise new matter. The importance of this element was thoroughly discussed in the previous Response and should have been considered by the Examiner. However, the Examiner seems to state that an explicit statement would make a difference in his consideration of the claims and so the claims have been so amended. The Examiner's reconsideration of the claims in view of these amendments by Applicant would be greatly appreciated.

Applicant strongly disagrees that the previous response did not comply with 37 CFR 1.111(b). Applicant clearly pointed out that the claim language "**to achieve controlled intermittent asystole**" clearly distinguishes the claimed devices over the cited prior art. This vital difference between the cited prior art and the claimed invention is discussed again below.

The Examiner has rejected all pending claims 1, 4-16, and 41-53 on the basis of obviousness over U.S. Patent No. 4,640,298 to Pless et al. ("Pless").

Pless

Pless teaches an electrode probe for stimulation of the heart from the interior of the esophagus. The stimulation is used for "patients with sudden instance of heart failure" (col. 1, ll. 22-24) to provide emergency pacing such as in cases of heart arrest (asystole) (col. 1, ll. 27- 29). The Pless device has two stimulation regions, one for the left atrium and one for the left ventricle (see claim 1 and FIGS. 1, 2, and 6). The focus of Pless is stated in col. 4, ll. 17-23:

> The invention is based on the surprising finding that while the distance from the wing of the nose to the heart, as measured through the esophagus, varies, as stated, from individual to individual, the distance from the transition between stomach and esophagus to the transition between left atrium and left ventricle is for practical purposes independent of the height of adults.

Pless differs from the presently claimed invention in several ways. Pless is designed to stimulate the heart, from placement inside the esophagus. Figure 6 especially illustrates this. The claimed invention, on the other hand, is for stimulation of the vagus nerve. Pless nowhere mentions stimulation of the vagus nerve.

Pless teaches using the device for the opposite reason of the claimed invention. Pless teaches using the device to apply electric current on a heart already in asystole (non-beating) or with an arrhythmic, irregular beat to guide the heart to regular beating. The Pless device is essentially a rapidly deployable pacemaker.

Conversely, the claimed invention's aim is to take a heart that is already beating in a normal fashion and stop it in a controlled way ("applying an electric pulse to the expandable electrode in order to achieve controlled intermittent asystole"). Controlled intermittent asystole (or CIA, using the acronym developed by the Applicant) is described in the present specification on page 2 of the specification. CIA is a way to "provide brief intervals of cardiac quiescence" so that cardiac motion can be minimized and procedures, such as bypass graft, can be performed more safely and accurately. The specification describes in detail how the claimed device can be used to achieve CIA.

The Examiner's argument is thus that Pless, which teaches application of a current to start the heart, teaches the claimed invention of a method to temporarily stop or slow the heart. The Examiner states that one skilled in the art would "have found it obvious to use the device to control intermittent asystole because Pless et al teach in case of asystole where the heart emits no EKG recordable impulses, stimulation signals will be applied by all the electrodes until the heart begins beating again and EKG signals can be recorded."

Applicant agrees that Pless teaches that in the case of asystole, the device can be used to start the heart beating again. But Pless does not teach or suggest that a state of CIA is desirable or can be achieved. Pless is concerned with getting the heart beating – not with getting the heart to temporarily stop or slow beating.

The claimed device is not to "control intermittent asystole" but rather to achieve "controlled intermittent asystole". The claimed device can be applied to a normal beating heart (via the vagus nerve) to achieve controlled intermittent asystole. Pless on the other hand teaches a device applied to a non-beating or irregularly beating heart. Pless does not teach how to achieve controlled intermittent asystole, but rather teaches achieving a regular heart beat.

Accordingly, Pless does not teach or render obvious the claimed invention and prompt allowance of the claims is warranted and appreciated.

Respectfully submitted,

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